Message

From: Culleen, Lawrence E. [Lawrence.Culleen@arnoldporter.com]
Sent: 12/12/2019 1:03:18 AM
To: Dekleva, Lynn [dekleva.lynn@epa.gov]
Subject: Revised Version of Consent Order
Attachments: Edited EPA draft Consent Order Dec. 2019 w_PAG Consort.Comments_(US_166798536_19).DOCX

Lynn --

Attached for your review and response is the draft Consent Order triggering Tiered Testing for 5 representative PAG substances. The PAG Consortium acknowledges and appreciates the changes made by EPA drafters in response to many of the concerns raised by the Consortium based on prior drafts.

In our effort to reach a resolution rapidly, and as a demonstration of our continuing efforts to make progress, we have made very few edits in the text and have inserted comments that appear in the margins of the draft attached when viewed in the "track changes" mode. For clarity, we did not "accept changes" in the draft you provided late in the afternoon on Friday November 22; rather, the PAG Consortium's proposed revisions to the Agency's November 22 draft were simply made "on top" of the various edits and comments previously inserted by the Agency. However, to simplify your review on the few edits we have made, any new inserts, edits, and comments are called out in the margins in the comment fields and are labelled in CAPITAL letters as "NEW COMMENTS FROM CONSORTIUM" or "NEW EDIT FROM CONSORTIUM". Moreover, such comments also appear in the margins in a blue font to distinguish them from previous comments offered by the Consortium or the Agency in the prior draft.

Below is a short list which highlights some of the areas of concern we think can be addressed successfully. This list is not exclusive, but includes those of perhaps the greatest concern to the Consortium Members. There may be some areas noted below that might not be easily addressed simply by accepting all of our proposed edits. To that end, we recommend scheduling a face-to-face meeting so we can confer directly with Agency personnel who are engaged on some of the more technical issues. Such a meeting might permit us to clarify some of our remaining questions and concerns quickly; this could help us reach a common understanding on these issues and the parties could adjust the language in the final Consent Order afterwards as needed.

1. Restoring the de minimis exemption from the Hazard Communications provisions. The PAG Consortium Members request the Consent Order draft be edited to reinsert the de minimis exemption from the hazard communications provisions. We have surveyed the PAG formulation producers and they have confirmed that, when distributed to customer/users in the semiconductor industry, the PAG compound is typically present only at very low concentrations in the formulation; generally at concentrations that are well below the 1.0% level ordinarily permitted in the de minimis exemption in the "boiler plate" version of the standard 5(e) Consent Order. This exemption is consistent with OSHA's Hazard Communications regulations. A de minimis exemption also appears in the Agency's TSCA Section 12(b) export notification rule, and numerous previously-issued Consent Orders. When distributed to users, formulations that contain PAG chemicals are delivered in small, sealed containers that do not have the room for, nor ordinarily bear, the elaborate labelling the draft Consent Order would require. Without the de minimis exemption, the Hazard Communications requirements in the draft Consent Order will present enormous challenges and impose unnecessary restrictions on the suppliers and users which are unrelated to actual workplace exposures and the conditions of use in the sector.

2. Limiting the number of substances to test within each Step or Tier. We continue to think it is both reasonable and prudent to limit the number of substances to be tested in any given Step or Tier to not exceed the number of substances that were identified for testing as representative PAGs. This approach would be

conducive to ensuring we focus our collective attention and limited resources only on substances of genuine concern and those potentially deserving further investigation. This also would be significantly helpful to the Consortium Members because the cost of the Tiered Testing set forth in the draft Consent Order is considerable. Nevertheless, you have advised us that the Agency is unwilling to commit to specific numerical limits on the number of substances subject to testing, such as we have previously proposed. (You also have advised us that the volume-based trigger we proposed for the initiating the higher level Tiers of testing was not agreeable.) In response, and based on our understanding of the Agency's good-faith commitment to avoiding requests for unnecessary studies, and its agreement to focus only on data gaps that are critical to enabling risk-based decision making for the PAG substances, we have inserted some edits to sub-paragraph (d)(2) in the "triggered testing" provisions. We understand this will be the operative paragraph guiding EPA's approach in its consultations with the Consortium and when considering whether additional studies in successive Steps or Tiers are needed for a specific substance. Our edits were modest, and reflect our understanding of EPA's perspectives in this regard.

3. Getting EPA's commitment on the scope of the PAG Category definition. The Agency and Consortium jointly developed the definition of the PAG Category which is reflected in this definitions section of the current draft Consent Order. The Consortium understood the Agency had agreed the 5 selected PAG substances were considered by EPA to be representative of the category; the selection of the substances was done collaboratively with the Agency so that testing on the representative PAGs would be considered sufficient to characterize the substances fitting within that definition. Unfortunately, we have learned from a Consortium member / PMN submitter very recently that a reported PAG which is within the scope of this definition (i.e., the substance is a sulfonium or iodonium salt) nevertheless might not be considered by Agency reviewers to be within the scope of the representative substances for purposes of the draft 5(e) Consent Order. Because the cost of the suite of studies requested in the Tiered Testing program is considerable, and the Consortium members have agreed to sharing certain costs only on those substances within scope of this agreement, the Consortium considers it to be imperative that we meet to address this unanticipated issue. Such a meeting should occur soon so we can resolve these concerns and favorably address the language of the Consent Order. Accordingly, given the impending winter holidays, the Consortium thinks it is appropriate to extend the time limitation on LVEs sufficiently beyond the end of the calendar year (perhaps for an additional 60 days) so we can convene a meeting to discuss and reach an understanding on this concern.

In closing, let me reiterate that I would be pleased to meet with you in your offices to go through the attached draft in detail to discuss the few changes we have proposed. The Consortium asks that if the few edits we have made are further modified, the Agency provide a responsive draft and include specific feedback in advance of submitting Consent Orders directly to individual Consortium Member / PMN Submitter. This will enable collaboration among the Consortium Members, hasten our review, and allow us to quickly respond and seek resolution on issues that ultimately will affect all Consortium Members (i.e., both the formulation producers and the users in the semiconductor sector who also are cooperating with this effort).

Thank you. I look forward to speaking with you soon.

Larry

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